# Workshop Goal

*Engage stakeholders in dialogue to assess the value and design of studies to evaluate placental transfer and potential clinical impact of drug and biologics with immunosuppressive properties on infants.*

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## Day 1  
**9:00 AM – 4:30 PM (ET)**

### Welcome & Introduction

<table>
<thead>
<tr>
<th>Time</th>
<th>Description</th>
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</table>
| 9:00 AM – 9:10 AM | **Welcome and Overview**  
Tamara Johnson, FDA          |
| 9:10 AM – 9:15 AM  | **Introductory remarks**  
Robert Califf, Commissioner of the FDA                                      |
| 9:15 AM – 9:35 AM  | **FDA Evaluation of In Utero Exposure to Drug and Biologic Products**  
Katie Kratz, FDA  
Sonaly McClymont, FDA      |

### Background Session: Background and Current Landscape

<table>
<thead>
<tr>
<th>Time</th>
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| 9:35 AM – 9:50 AM | **Mechanisms of Placental Transfer for Small Molecules and Biologics**  
Leslie Myatt, Oregon Health & Science University |
| 9:50 AM – 10:10 AM | **Placental Transfer of Immunosuppressive Small Molecules: Current Clinical Pharmacology Landscape**  
Raman Venkataramanan, University of Pittsburgh |
| 10:10 AM – 10:30 AM | **Placental Transfer of Immunosuppressive Biologics: Current Clinical Pharmacology Landscape**  
Edwin Lam, J&J Innovative Medicine |
| 10:30 AM – 10:50 AM | **Current Clinical Landscape**  
Uma Mahadevan, UCSF |
| 10:50 AM – 11:05 AM | **Benefit-Risk Conceptual Framework for In Utero Exposure of Biologics**  
Laura Bozzi, J&J Innovative Medicine |
| 11:05 AM – 11:25 AM | **BREAK** |

### Session 1: Value – Current Clinical and Safety Considerations

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<tbody>
<tr>
<td>11:25 AM – 12:10 PM</td>
<td><strong>Panel Discussion</strong></td>
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**Moderator:** Leyla Sahin, FDA  
**Panelists:**  
- Uma Mahadevan, UCSF  
- Kevin Ault, Western Michigan University  
- Latéy Bradford, University of Maryland  
- Natalie Hayden, Patient Representative  
- Vani Vannappagari, ViiV Healthcare  
- Maria Fernanda Scantamburlo Fernandes, Eli Lilly

12:10 PM – 1:10 PM  
LUNCH

### Session 2: Nonclinical Evaluation of Placental Transfer and Immunotoxic Potential

1:10 PM – 1:25 PM  
**Relevant In Vitro and Ex Vivo Assessments for Small Molecules and Biologics**  
*Nick Illsley, NJ Medical School, Rutgers Univ, Placental Research Group LLC*

1:25 PM – 1:40 PM  
**In Silico Assessments for Small Molecules and Biologics**  
*Rohan Lewis, University of Southampton*

1:40 PM – 2:00 PM  
**In Vivo Animal Assessments**  
*John DeSesso, Exponent Consulting Company*

2:00 PM – 2:15 PM  
**Nonclinical Guidances Pertinent to Developmental Immunotoxicity**  
*David McMillan, FDA*

2:15 PM – 2:55 PM  
**Panel Discussion**  
**Moderator:** Jashvant Unadkat, University of Washington  
**Panelists:**  
- Nick Illsley, NJ Medical School, Rutgers Univ, Placental Research Group LLC  
- Rohan Lewis, University of Southampton  
- John DeSesso, Exponent Consulting Company  
- David McMillan, FDA  
- Dinesh Stanislaus, GSK

2:55 PM – 3:15 PM  
BREAK

### Session 3: Framing Concerns for In Utero Exposed Infants Based on Available Data

3:15 PM – 4:00 PM  
**Panel Discussion**  
**Moderator:** Kelly Stone, FDA  
**Panelists:**  
- Mike Keller, Children’s National/George Washington University  
- Ofer Levy, Boston Children’s/Harvard University  
- Jeff Roberts, Merck

4:00 PM – 4:15 PM  
**Day 1 Closing Remarks**  
*Tamara Johnson, FDA*
### Day 2  
**9:00 AM – 1:00 PM (ET)**

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<td>Tamara Johnson, FDA</td>
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#### Session 4: Clinical Study Design Considerations

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<tr>
<td>9:10 AM – 9:20 AM</td>
<td>Ethical Considerations for Clinical Investigations in Children to Assess the Impact of Placental Transfer of Drugs and Biologics with Immunosuppressive Properties</td>
<td>Melanie Bhatnagar, FDA</td>
</tr>
<tr>
<td>9:20 AM – 9:40 AM</td>
<td>How Can We Predict Fetal Drug Exposure Throughout Pregnancy To Inform Potential Fetal Toxicity?</td>
<td>Jashvant Unadkat, University of Washington</td>
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<tr>
<td>9:40 AM – 10:00 AM</td>
<td>Clinical Pharmacology and Modelling of Drug Transfer Across the Placenta: Biologics</td>
<td>Ruth Oliver, Takeda</td>
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</tbody>
</table>
| 10:00 AM – 11:05 AM | Panel Discussion                                                     | **Moderators:** Lily Mulugeta, FDA & Sonaly McClymont, FDA  
                     | **Panelists:**                                                       | - Jashvant Unadkat, University of Washington       
                     | - Ruth Oliver, Takeda                                                | - Joseph Cafone, J&J Innovative Medicine           
                     | - Mona Khurana, FDA                                                 | - Elisa Ochfeld, Children’s Hospital of Philadelphia |

#### Session 5: Logistical Considerations, Future Directions, and Next Steps

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<td>11:05 AM – 11:25 AM</td>
<td>BREAK</td>
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| 11:25 AM – 12:50 PM | Panel Discussion                                                     | **Moderator:** Lynne Yao, FDA  
                     |                                                      | **Panelists:**  
                     |                                                      | - Robert “Skip” Nelson, J&J Innovative Medicine  
                     |                                                      | - Marie Teil, UCB  
                     |                                                      | - Kevin Ault, Western Michigan University  
                     |                                                      | - Ofer Levy, Boston Children’s/Harvard University  
                     |                                                      | - Aaron Pawlyk, NICHD  
                     |                                                      | - Natalie Hayden, Patient Representative  
                     |                                                      | - Giorgia Berardi, EU Network – Italian Medicines Agency |
| 12:50 PM – 1:00 PM | Closing Remarks                                                      | Tamara Johnson, FDA                                                                                   |